

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF MICHIGAN  
SOUTHERN DIVISION**

JEANNA NORRIS, KRAIG EHM,  
D'ANN ROHRER, *et al.*,

*Plaintiffs,*

v.

SAMUEL STANLEY, *et al.*,

*Defendants.*

HON. PAUL MALONEY, U.S.D.J.

Civil Action No.  
1:21-cv-00756

**PLAINTIFFS' RESPONSE IN OPPOSITION TO  
DEFENDANTS' MOTION TO DISMISS**

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## BACKGROUND

Last winter, FDA approved three vaccines pursuant to the federal Emergency Use Authorization (EUA) statute, 21 U.S.C. § 360bbb-3: the Pfizer BioNTech, Moderna, and Johnson and Johnson (Janssen) vaccines. *See* First Amended Complaint, ECF No. 55 at ¶ 20 (“FAC”). Pfizer’s Comirnaty Vaccine received full FDA approval on August 23, 2021. *Id.* at ¶ 20(d).

EUAs allow FDA to make a product available to the public following a truncated testing process, and based on the best available data, without waiting for all the evidence needed for full FDA approval or clearance. FDA, *Emergency Use Authorization for Vaccines Explained* (Nov. 20, 2020), *available at* [bit.ly/3x8wImn](https://bit.ly/3x8wImn) (last visited August 26, 2021). *See* FAC at ¶¶ 23-30 (for a more detailed explanation of the differences between EUA and full FDA approval). Products granted an EUA have *not* been proven safe and effective. *See* “Memorandum Opinion for the Deputy Counsel to the President,” *Whether Section 564 of the Food, Drug, and Cosmetic Act Prohibits Entities from Requiring the Use of a Vaccine Subject to an Emergency Use Authorization* (July 6, 2021) (OLC Op.) at 7-13, *available at* <https://www.justice.gov/olc/file/1415446/download> (last visited Aug. 1, 2021).

There has been significant confusion over whether the BioNTech and Comirnaty vaccines are, in actuality, the same. In a letter to Pfizer, FDA stated that “the Pfizer-BioNTech COVID-19 Vaccine that uses PBS buffer and COMIRNATY (COVID-19 Vaccine, mRNA) have the same formulation. The products are legally distinct with

certain differences that do not impact safety or effectiveness.” (emphasis added). FDA, “Letter to Pfizer, Inc.” (October 29, 2021), *available at* <https://www.fda.gov/media/150386/download> (last visited Nov. 4, 2021). *See* FAC ¶ 21.

Generally speaking, certain drugs that the public believes are identical—generic versions of brand name drugs for instance—do not need to be formulaically identical to be considered “equivalent.” FDA, “Generic Drugs: questions & Answers,” *available at* <https://www.fda.gov/drugs/questions-answers/generic-drugs-questions-answers#q5> (last visited Nov. 4, 2021). *See* FAC ¶ 21(c). Despite Pfizer’s proclamations to the contrary, an analysis of the ingredients in the Comirnaty and BioNTech vaccines indicates they are not, in fact, identical. Recently, a court recognized as much, explaining that inactive ingredients may differ in these circumstances, which can translate into a difference in safety and efficacy. *See Doe v. Austin*, No. 3:21-cv-1211-AW-HTC (Nov. 12, 2021), fn. 5.

The Comirnaty Vaccine is *not* widely available due to limited supply. Pfizer itself has stated that “there is not sufficient approved vaccine [the Comirnaty] available for distribution to this population in its entirety at the time of the reissuance of this EUA.” *See id.* at p. 9 fn. 7. *See also* FDA, *FDA Approves First COVID-19 Vaccine*, (Aug. 23, 2021), *available at* <https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine> (last visited Oct. 29, 2021). *See* FAC ¶ 21(a). In fact, the Task Force Guidance governing the federal employee mandate acknowledges that

individuals, depending on their geographic location, may not have access to any specific COVID-19 vaccine: employees “may not have all types of vaccines available to them. Agencies should encourage employees to plan ahead and allow enough time to receive all required vaccine doses before the November 8 deadline to have their second shot.” United States Government, “Safer Federal Work Force,” *available at* <https://www.saferfederalworkforce.gov/faq/vaccinations/> (last visited Nov. 3, 2021). *See* FAC ¶ 21(b).

All medical procedures, including immunizations, carry some risk of side effects. Though the COVID-19 vaccines appear to be relatively safe at a population level, as with all medical interventions, some individuals will suffer adverse consequences, even severe ones. Such side effects may include common, temporary reactions such as pain and swelling at the vaccination site, fatigue, headache, muscle pain, fever, and nausea. While rarer, they can also cause serious side effects that result in hospitalization or death. Declaration of Drs. Martin Kulldorff and Jayanta Bhattacharya, FAC Attachment A (“Joint Decl.”) ¶¶ 25-26.

The vaccines may very well cause long-term side effects that remain unknown at this time due to their relatively recent development. Joint Decl. ¶¶ 26-27. Put differently, as a matter of simple logic, it is not possible to be certain about the long-term effects of a vaccine that has not been in existence for the long term, and thus cannot have been studied over a span of years. For that reason, “[a]ctive investigation to check for safety problems is still ongoing.” Joint Decl. ¶ 26.

Indeed, just this week the CDC sidelined the Johnson and Johnson vaccine over concerns about blood clotting issues. “US panel recommends J & J Shots be sidelined after clot deaths,” *BBC News* (Dec. 16, 2021), *available at* <https://www.bbc.com/news/world-us-canada-59692776> (Dec. 17, 2021). This underscores the reality that safety investigations are ongoing for these vaccines, and new information could surface at anytime.

Recent research indicates that vaccination presents a heightened risk of adverse effects—including serious ones—to those who have previously contracted and recovered from COVID-19. Joint Decl. ¶ 28; FAC Attachment B (“Noorchashm Decl.”) ¶¶ 21-26; FAC Attachment C (“Bhattacharya Decl.”) ¶ 30. The heightened risk of adverse effects results from “preexisting immunity to SARS-Cov-2 [that] may trigger unexpectedly intense, albeit relatively rare, inflammatory and thrombotic reactions in previously immunized and predisposed individuals.” Angeli, *et al.*, *SARS-CoV-2 Vaccines: Lights and Shadows*, 88 *EUR. J. INTERNAL MED.* 1, 8 (2021). *See also* Jennifer Block, “Vaccinating people who have had covid-19: why doesn’t natural immunity count in the US?” *BRITISH MEDICAL JOURNAL* (Sept. 13, 2021), *available at* <https://www.bmj.com/content/374/bmj.n2101> (last viewed Dec. 13, 2021) (hereinafter “Block article”) (citing several experts and studies establishing that those who have previously been infected are more likely to experience adverse side effects from the vaccine).



As discussed extensively in the FAC and recognized both historically in the context of other diseases and most recently by several federal courts, overwhelming scientific research establishes that immunity following a COVID-19 infection is equivalent to or perhaps better than that attained through vaccination. FAC ¶ 35-68. *See BST Holdings v. OSHA*, No. 21-60845 (Nov. 12, 2021) (“a naturally immune unvaccinated worker is presumably less at risk than an unvaccinated worker who has never had the virus.”); *Louisiana v. Becerra*, No. 3:21-cv-03970 (Nov. 30, 2021) (“the rejection of natural immunity as an alternative is puzzling”); *Missouri v. Biden*, 2021 WL 5564501 (E.D. Mo. Nov. 29, 2021) at p. 17 and fn. 20, *aff’d Missouri v. Biden*, No. 21-3725 (8<sup>th</sup> Cir. Dec. 13, 2021) (finding that CMS changing its posture with respect to natural immunity constituted evidence of unlawful agency action, and noting that “CMS also rejected natural immunity, despite an intense public debate and a trove of scientific data on the strength and durability of natural immunity from COVID-19—alone and compared to vaccine-induced immunity.”). Indeed, the District Court in *Becerra* queried why, “[i]f boosters are needed six months after being ‘fully vaccinated,’ then how good are the COVID-19 vaccines, and why is it necessary to mandate them?” *Becerra*, No. 3:21-cv-03970 at 26.

As further evidence that natural immunity is robust and durable, the CDC recently acknowledged that it was *unable to document even a single case* of a covid-recovered, unvaccinated individual spreading the virus to another person. *See* 11/5/21 Letter of Roger Andoh in Response to FOIA Request, attached as Ex. A). The significance of

CDC's admission cannot be overstated, given that risk of transmission to third parties is the sole justification for mandating an individual to take the vaccine against their will.

MSU is a public research university located in East Lansing, Michigan. In emails and on its website, MSU explicated its vaccine mandate ("the Directive") on July 30, 2021 and August 5, 2021. The Directive required all faculty, staff, and students to be fully vaccinated or obtain an approved exemption for the Fall 2021 semester by August 31, 2021. As a blanket rule, naturally acquired immunity is explicitly excluded as the basis for an exemption according to the University's FAQ page on the subject. Likewise, employees who work entirely from a remote location must comply with the Directive. *See* MSU Covid Directives, FAC Exhibits G-I.

However, MSU accepts as sufficient to satisfy its requirement non-FDA approved, inferior foreign vaccines such as the Sinovac and Sinopharm, which have approximately 50% efficacy rates. FAC ¶¶ 60-65, *citing* Joint Decl. ¶ 37, Noorchashm Decl. ¶ 29-31. It also accepts the Janssen vaccine, estimated to be about 66% effective at best. *See* FAC ¶ 60, *citing* Joint Decl. ¶ 16, Noorchashm Decl. ¶ 15.

In recognition of the highly protective character of natural immunity, the European Union has recognized "a record of previous infection" as a substitute for any vaccine passport requirements. Noorchashm Decl. ¶ 27. Israel, too, exempts from vaccination requirements those who are COVID-19 recovered. *See, e.g.,* "Covid passports: How do they work around the world?", *BBC News* (July 26, 2021), *available at* <https://www.bbc.com/news/world-europe-56522408>. Even France's controversial

new restrictive mandate on the ability to participate in daily life focuses on a person's immunity rather than their vaccine status—treating natural immunity and vaccine immunity equally. *See, e.g.,* Clea Callcutt, *France forced to soften rules after coronavirus green pass backlash*, POLITICO (July 20, 2021), *available at* <https://politi.co/3f9AZzS> (last visited July 29, 2021).

The Plaintiff class representatives in this case are as follows. Jeanna Norris, a 37-year old supervisory Administrative Associate and Fiscal Officer at MSU, where she has been employed for eight years. *See* FAC ¶¶ 72-81. She recovered from a bout of COVID-19 in November 2020, has naturally acquired immunity, and as a result does not wish to receive a COVID-19 vaccine. *See id.* On information and belief, on November 18, 2021, she applied for a religious exemption from the vaccine requirement, after commencing litigation in this case, and her request was granted on the following day.<sup>1</sup>

Plaintiff Kraig Ehm is a video producer for MSU, where he has been employed for 21 years. *See* FAC ¶¶ 82-84. He had COVID-19 in April 2021, and thereby acquired natural immunity to the virus. *Id.* Ehm underwent disciplinary proceedings at MSU because he declined to receive a vaccine, and was terminated from his position on November 3, 2021 for failure to comply with the Directive. *Id.*

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<sup>1</sup> Ms. Norris maintains standing in this case because exemptions may be rescinded, because she is not guaranteed the same treatment as individuals who have received the vaccine, and because she has an interest in seeing her natural immunity recognized as such, whatever policies Defendants may adopt.

Plaintiff D’Ann Rohrer is an Extension Educator at MSU, where she worked for 6 years. Ms. Rohrer had COVID-19 in August of 2021, and thereby acquired natural immunity to the virus. FAC ¶¶ 85-87. On information and belief, she was terminated by MSU on November 5, 2021 for failure to comply with the Directive.

### **STANDARD OF REVIEW**

A motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) should not be granted “unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.” *DirecTV, Inc. v. Treesh*, 487 F.3d 471 (6<sup>th</sup> Cir. 2007), *quoting Ricco v. Potter*, 377 F.3d 599, 602 (6<sup>th</sup> Cir. 2004). In evaluating such a motion, the court must “construe the complaint in the light most favorable to the plaintiff, accept its allegations as true, and draw all reasonable inferences in favor of the plaintiff.” *DirecTV, Inc.*, 487 F.3d at 476. The burden is on the defendant to show that the plaintiff has failed to state a claim for relief. *Id.*, *citing Carver v. Bunch*, 946 F.2d 451, 454-55 (6<sup>th</sup> Cir. 1991). The court “need not accept as true legal conclusions or unwarranted factual inferences.” *Gregory v. Shelby County*, 220 F.3d 433, 446 (6<sup>th</sup> Cir. 2000). This standard is, of course, vastly different from that used to grant a preliminary injunction. *See Arnold v. Heyns*, 2015 WL 4243269 (E.D. Michigan 2015), *citing Leary v. Daeschner*, 228 F.3d 729, 739 (6<sup>th</sup> Cir. 2000) (“the proof required for a plaintiff to obtain a preliminary injunction is much more stringent than the proof required to survive a dispositive motion.”); *Merck Sharp & Dohme Corp. v. Conway*, 2012

WL 1029427, fn. 5 (E.D. Kentucky 2012) (“the standard [plaintiff must satisfy] for a motion to dismiss is much lower than that for a motion for a preliminary injunction.”).

After reviewing the complaint and drawing all inferences in the plaintiffs’ favor, the court may dismiss the complaint *only if* the plaintiffs have “failed to set forth fair notice of what the claim is and the grounds upon which it rests that make such a claim plausible on its face.” *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). A complaint will survive a motion to dismiss if it contains sufficient factual matter to state a claim for relief that is plausible on its face and provides more than labels and conclusions or a formulaic recitation of the elements of a cause of action. *Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009). The rules do not require a probability of success but simply “more than a mere possibility that a defendant has acted unlawfully.” *Twombly*, 550 U.S. at 556.

## ARGUMENT

### **I. WHAT LEVEL OF SCRUTINY SHOULD APPLY TO PLAINTIFFS’ CLAIMS REMAINS AN OPEN QUESTION, BUT MSU’S VACCINE POLICY DOES NOT EVEN SURVIVE RATIONAL BASIS REVIEW**

Defendants argue that “mandatory vaccination requirements like MSU’s do not implicate an individual’s fundamental rights and thus are constitutional so long as they satisfy rational basis scrutiny.” *See* Def. MTD at 10. That there appears to be a “battle of the experts” with respect to the degree of immunity that natural infection confers, they argue, means that MSU has satisfied rational basis review. *See id.* On these grounds,

they claim that there is no view of the facts on which Plaintiffs' argument that the University's vaccine mandate violates their rights to bodily autonomy and to decline medical treatment under the Ninth and Fourteenth Amendment to the United States Constitution can survive a motion to dismiss. *See* Def. MTD at 10-15.

### **A. Whether Strict Scrutiny or Rational Basis Analysis Applies to COVID-19 Vaccine Mandates Is Unresolved**

Our nation has never before seen vaccine mandates like those now proliferating throughout the nation, involving entirely new EUA-approved vaccines<sup>2</sup> for a disease that does not present a deadly threat to most people, and with such vaccines appearing to be relatively ineffective at stopping transmission. None of the cases at hand involved vaccines approved under an EUA, nor did they involve vaccines that had existed for less than two years, meaning that, by definition, their long-term effects cannot be known. There is also no prior history of widespread employer vaccine mandates such as the one that MSU has implemented.

*Jacobson v. Massachusetts* was decided in 1905, at a time when interracial marriage was illegal in many states and women did not have the right to vote at the federal level. 197 U.S. 11 (1905). Much has changed since that time, including our concept of the importance of bodily autonomy, the right to decline medical treatment, and the science of detecting antibodies. Plaintiffs do not ask this Court to overturn *Jacobson*—contrary to Defendants' contentions (*see* Def. MTD at 12)—but rather to limit it to its time and

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<sup>2</sup> *See* Point III.

circumstances and harmonize it with more recent court precedents. We also ask this Court to recognize the framework in which *Jacobson* was decided, including the fact that it was *a statute* at issue (rather than an administrative edict), the lethality and nature of the disease being considered, and the medical advancements made since 1905.

Even on its own terms, *Jacobson* did not purport to stand for the proposition that all vaccine mandates are always legal. Rather, the decision made clear that there may be circumstances in which such mandates violate constitutional rights. *See Jacobson*, 197 U.S. at 28 (“it might be that an acknowledged power of a local community to protect itself against a[n] epidemic threatening the safety of all might be exercised in particular circumstances and in reference to particular persons in such an arbitrary, unreasonable manner, or might go so far beyond what was reasonably required for the safety of the public, as to authorize or compel the courts to interfere for the protection of such persons.”).

Several cases, post-dating *Jacobson*, confirm that not all vaccine mandates are subject only to rational basis review. *Cruzan v. Dir., Mo. Dep’t of Public Health*, 497 U.S. 261, 278 (1990) explicitly stated that the Constitution protects a person’s right to “refus[e] unwanted medical care.” *See King v. Rubenstein*, 825 F.3d 206, 222 (4th Cir. 2016) (recognizing same). This right is “so rooted in our history, tradition, and practice as to require special protection under the Fourteenth Amendment.” *Washington v. Glucksberg*, 521 U.S. 702, 722 n.17 (1997). The Court has explained that the right to refuse medical care derives from the “well-established, traditional rights to bodily

integrity and freedom from unwanted touching.” *Vacco v. Quill*, 521 U.S. 793, 807 (1997).

Given that in the last 115 years of jurisprudence and medical advancement the courts have issued numerous decisions taking a vastly different approach to notions of bodily integrity, at the very least this question deserves to be fully litigated to take into consideration these developments. The claim certainly cannot properly be done away with via a motion to dismiss. *See BST Holdings*, No. 21-60845 \* 18 (granting preliminary injunction because being forced to choose between vaccination and employment entailed a loss of constitutional freedoms, *even though* masking and testing was offered as an alternative to vaccination); *Louisiana v. Becerra*, No. 3:21-cv-03970 (“The Plaintiff States’ citizens will suffer irreparable injury by having a substantial burden placed on their liberty interests because they will have to choose between losing their jobs or taking the vaccine.”); *Missouri v. Biden*, 2021 WL 5564501 (granting Plaintiffs’ motion to preliminarily enjoin CMS mandate).

### **B. MSU’s Vaccine Directive Does Not Satisfy Rational Basis Review**

The government must justify the imposition of an intrusive mandate such as the Directive at issue here. *Even if* rational basis review were to apply (which it doesn’t), MSU has not satisfied its burden. Defendants, attempting to justify their mandate, conflate the notion of stemming the spread of COVID-19 with the threat that the virus poses to unvaccinated individuals. Indeed, they state that “COVID-19 is still a threat to people who are unvaccinated,” Def. MTD at 6, an implicit concession that the virus



does not pose a significant danger to the vaccinated. But if COVID-19 poses a threat only to the unvaccinated—and the vaccines protect any individual who receives them—then there is no state interest in mandating vaccines for everyone. The government (including a state actor like MSU) is not entitled to insert itself into our personal health decisions, especially when those decisions affect each of us individually. To hold otherwise would be to allow the State to wield unconstrained and unconstrainable power over the lives of each and every one of us. Why, if the individual’s physical health may be the subject of a mandate, should not daily exercise be required, or a mandate for a certain amount of green vegetables consumption be implemented? Obesity is one of the most significant risk factors for a severe COVID-19 infection, but no serious person has suggested mandating that we all maintain a BMI below a certain level; to even consider such a concept is ludicrous. *See* Roni Caryn Rabin, “The Coronavirus Attacks Fat Tissue, Scientists Find,” *The New York Times* (Dec. 8, 2021).

The Missouri District Court has enjoined the federal CMS mandate, thereby recognizing as much when it stated: “the lack of data regarding vaccination status and transmissibility—in general—is concerning” and “CMS also admits that the continued efficacy of the vaccine is uncertain.” *See Missouri v. Biden*, 2021 WL 5564501 (E.D. Mo. Nov. 29, 2021) at 15-16. *See also* Bhattacharya Decl. ¶¶ 23-24 (“the evidence to date suggests that while vaccines—like natural immunity—provide strong protection against severe disease, they, unlike natural immunity, provide only short-lasting protection against subsequent infection and disease spread.”).

The *Jacobson* decision was based in part on the existence of ample proof that the smallpox vaccine was sterilizing, meaning that it stopped or significantly slowed transmission. See *Jacobson*, 197 U.S. at 32 (“the principle of vaccination as a means to prevent the spread of smallpox has been enforced in many states” and “[i]f vaccination strongly tends to prevent the transmission or spread of this disease, it logically follows that children may be refused admission to the public schools until they have been vaccinated.”). Defendants provide no such scientific evidence here. Quite the contrary. See *Missouri v. Biden*, 2021 WL 5564501 (quoting CMS’s own statements acknowledging that “the effectiveness of the vaccine to prevent disease transmission by those vaccinated [is] not currently known.”). Their legal arguments are also premised upon the benefit to the *individual* of receiving the vaccine, which again cannot be reconciled with their claim that the justification for a mandate is danger the unvaccinated pose to others.

It is also important to recognize that the Supreme Court requires a District Court to exclude evidence that does not meet the *Daubert* criteria for reliability. *Daubert v. Merrell Dow Pharmaceuticals Inc.*, 509 US 579 (1993). The “science” used to assert this vast power of forced vaccination has not been tested either at a *Daubert* hearing or at trial. There are facts that, if proven, would invalidate this policy under any standard. If naturally acquired immunity is as effective as (or more effective than) the vaccines at halting transmission, then there is no justification for the Directive, and it cannot survive rational basis review. Notably, Defendants do not contend that MSU’s

Directive would satisfy strict scrutiny level analysis. *See BST Holdings*, No. 21-60845 \*13 (finding Biden’s OSHA mandate “staggeringly overbroad” as, *inter alia*, a “a naturally immune unvaccinated worker is presumably at less risk than an unvaccinated worker who has never had the virus. The list goes on, but one constant remains—the Mandate fails almost completely to address, or even respond to, much of this reality and common sense.”); *Kentucky v. Biden*, No. 3:21-cv-00055 \* 13 (Nov. 30, 2021) (citing as evidence that the Biden mandate did not accomplish goals of statute through which it was implemented that the “applies to employees of federal contractors and subcontractors who work entirely from home and are not at risk of spreading COVID-19 to others.”).

Oddly enough, Defendants point to Plaintiffs’ statements acknowledging that the coronavirus presents a serious threat to public health and that the vaccines are an effective means of mitigating that danger. *See* Def. MTD at 12-13. Once again, this is a conflation of two separate notions. That the vaccines are potentially effective instruments for individuals to *choose to take in order to reduce their own risk*, depending on their specific circumstances, does not mean that blanket mandates—particularly those that do not provide exemptions for those with naturally acquired immunity—are an effective means of addressing the crisis. Both the Missouri and Louisiana District Courts, enjoining the CMS mandate, observed that workplace vaccine requirements tend to be counterproductive. *See Missouri v. Biden*, 2021 WL 5564501 (“[b]y dispensing with [notice and comment] requirements, CMS ignored evidence showing that the mandate threatens devastating consequences to healthcare providers, staff, and patients

throughout the nation.”); *Louisiana v. Becerra*, No. 3:21-CV-03970 (W.D. Louisiana 2021) (finding that CMS mandate is arbitrary and capricious because, *inter alia*, implementing statute was designed to protect patients, while the mandate is likely to result in shortages of healthcare workers and thereby harm patients).

Defendants argue that their policy, insofar as it does not carve out an exemption for the naturally immune, withstands rational basis level review because experts differ as to whether individuals who have naturally acquired immunity should get the vaccine. They do not address the fact that transmissibility seems unaffected by vaccination as compared to naturally acquired immunity. As an initial matter this is a factual dispute, and given that this case is at the motion to dismiss stage, any and all facts involved must be viewed in the light most favorable to Plaintiffs. Construed in this manner, naturally acquired immunity is equally or more protective to that achieved through vaccination. *See DirecTV*, 487 F.3d 471 (“unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitled him to relief” and the court must “construe the complaint in the light most favorable to the plaintiff, accept its allegations as true, and draw all reasonable inferences in favor of the plaintiff.”).

In any event, Defendants’ position is based on a fundamental misapprehension of a crucial issue. They confuse raised antibody levels, which may or may not translate into a marginal clinical benefit, with justification for a *mandate*. True, some experts recommend that even those who have had COVID-19 get a vaccine to *boost* their antibody levels for their personal protection. But antibody levels could always be

boosted—even to dangerous levels—but that does not necessarily offer more protection, as the immune system is very complex and not limited to generation of antibodies. *See* Bhattacharya Decl. ¶¶ 14. Furthermore, this is true of those who have had the vaccine, as well. Whether the vaccine’s temporarily raising antibody levels justifies a *mandate*—which involves intrusion into an individual’s personal medical decisions—is another matter, and in fact the one in question.

Vaccination of the naturally immune may be counterproductive. Some experts believe that subsequent vaccination (especially a two-dose regimen) for those who have been previously infected may cause “‘exhaustion,’ and in some cases even a deletion, of T-cells,” leading to a depleted immune response. Block Article. *See* Reply to Preliminary Injunction Opposition, Attachment A, ECF No. 11-3, Reply Decl. Hooman Noorchashm (“Reply Decl.”) ¶¶ 18-23. Combined with the documented, heightened risk of adverse effects that those with naturally acquired immunity face, there is a strong argument that requiring the naturally immune to receive vaccines also entails additional violations of fundamental, constitutional rights, *since vaccination could make this subpopulation more susceptible to reinfection.*

Defendants likewise misrepresent the outlier Kentucky study that the CDC has touted as substantiating MSU’s Directive. *See* Def. MTD at 14. This study was wrongly interpreted and incorrectly portrayed by the media. Contrary to Defendants’ claims, Plaintiffs did not “admit that at least one scientific study concludes” naturally acquired immunity is inferior to the vaccines. Rather, Plaintiffs explained why the CDC

misrepresented the results of that study to reach the conclusion that it sought, including that the CDC had data from all 50 states but released the results of the only one (Kentucky) that could be construed as supporting its position. *See* FAC ¶ 136, *citing* Joint Decl. ¶ 37, Noorchashm Decl. ¶¶ 29-31, Bhattacharya Decl. ¶¶ 47-48. *See also* Marty Makary, “Covid Confusion at the CDC,” *The Wall Street Journal* (Sept. 13, 2021), *available at* <https://www.wsj.com/articles/covid-19-coronavirus-breakthrough-vaccine-natural-immunity-cdc-fauci-biden-failure-11631548306> (last visited Nov. 3, 2021.) Furthermore, the study “did not address or attempt to quantify the magnitude of risk and adverse effects in its comparison groups,” Noorchashm Decl. ¶¶ 29-31, as the study did not compare vaccinated individuals to COVID-recovered individuals. It also did not control for the fact that the vaccinated are “possibly less likely to get tested. Therefore, the association of reinfection and lack of vaccination might be overestimated.” Block article.

In a similar sleight of hand, Defendants argue that “Plaintiffs concede that they lack certainty that they will not transmit the virus to others,” to justify their vaccine mandate. Def. MTD at 14. Of course Plaintiffs lack total certainty. Even if they were vaccinated, both they and the CDC would still lack certainty that they were unable to become infected and transmit the virus. Little, if anything, in science or medicine is *certain*. Defendants cannot claim that those who have been vaccinated will definitely not transmit the virus, and as the real-world evidence is showing, precisely the opposite appears to be true: vaccinated people are spreading the virus, as even the CDC

acknowledges. *See, e.g.*, “Delta Variant: What We Know About the Science,” *CDC* (Aug. 26, 2021), *available at* <https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html> (last viewed Dec. 15, 2021) (“[f]ully vaccinated people with Delta variant breakthrough infections can spread the virus to others.”). At the same time, it has no record of those with natural immunity doing so. *See* Ex. A.

Every day, the evidence establishing the robustness and durability of naturally acquired immunity, and relative inferiority of vaccine-induced immunity (hence the discussion of a fourth round of shots), grows. All real-world evidence points to the fact that naturally immune people only become reinfected on extremely rare occasions and do not transmit the virus. The so-called evidence that naturally immune people should receive the vaccine is at best theoretical, and not borne out by real world observations. *See* Ex. A. *See also, e.g.*, Bhattacharya Decl. ¶ 16 (citing a study from Israel of 6.4 million individuals, in which half a percent of those with naturally acquired immunity were reinfected, much less than reinfections among the vaccinated).

Accordingly, *even if* rational basis review applies, MSU’s policy cannot survive it. *See* Paul Elias Alexander, “137 Research Studies Affirm Naturally Acquired Immunity to Covid-19,” *Brownstone Institute* (Oct. 17, 2021), *available at* <https://brownstone.org/articles/79-research-studies-affirm-naturally-acquired-immunity-to-covid-19-documented-linked-and-quoted/> (last viewed Dec. 15, 2021). Plaintiffs have, in fact, “negate[d] every conceivable basis which might support” MSU’s policy. The approach that MSU has taken means that the university could mandate the

vaccine for each employee every day—because it would boost their antibody levels. At the very least, the question warrants further litigation and cannot be resolved at this stage.

## **II. CONTRARY TO DEFENDANTS’ CLAIMS, MSU’S VACCINE DIRECTIVE CONSTITUTES AN UNCONSTITUTIONAL CONDITION**

Defendants’ arguments on this point are based on a misunderstanding or misportrayal of various aspects of unconstitutional conditions doctrine. *See* Def. MTD at 15-16. They contend that Plaintiffs’ claims fail because: (1) they have failed to identify an enumerated right that the vaccine policy coerces them into giving up; (2) they have not established that they are being coerced into surrendering rights that the law deems fundamental or any rights at all; and (3) they have not alleged facts giving rise to an inference of coercion. All these arguments rest upon flawed premises.

### **A. Plaintiffs Do Not Have to Allege Violation of an Enumerated Right in Order to Succeed on this Claim**

As established by *Memorial Hosp. v. Maricopa Cty*, 415 U.S. 250 (1974), the right that Plaintiffs allege MSU’s Directive violates need not be enumerated in the United States Constitution. In *Maricopa*, the right in question was that to interstate travel, alleged under the Fourteenth Amendment—unquestionably not a specifically enumerated right. Defendants simply ignore the existence of this case, presumably because it cannot be reconciled with their contentions.

Instead, their claims rest on *Koontz v. St. Johns River Water Mgmt. Dist.*, 579 U.S. 595, 604 (2013), in which the Court stated that *Maricopa County* and other cases “reflect



an overarching principle, known as the unconstitutional conditions doctrine, that vindicates the Constitution’s enumerated rights by preventing the government from coercing people into giving them up.” Nowhere in *Koontz* does the Court state that the right in question *must* be enumerated. There is no reason to believe that in *Koontz* the Court intended to overrule *Maricopa County*. The two should thus be read together, yielding the result that while the right that is leveraged *may* be enumerated, it does not have to be. *See also Regan v. Taxation With Representation of Wash.*, 461 U.S. 540, 454 (1983) (“the government may not deny a benefit to a person because he exercises *a constitutional right*.”) (emphasis added); *R.S.W.W. v. City of Keego Harbor*, 397 F.3d 427, 434 (2005)((“[unconstitutional conditions] doctrine should equally apply to prohibit the government from conditioning benefits on a citizen’s agreement to surrender due process rights.”).

## **B. Constitutional Rights Are at Issue Here**

Defendants’ contention that no constitutional rights are at issue fares no better. Plaintiffs acknowledge that whether the rights in question—to decline medical treatment and to protect bodily integrity when one has naturally acquired immunity to the disease in question—are fundamental is a live one. But even this Court, in denying the motion for a preliminary injunction, acknowledged that Plaintiffs possessed those rights. It held that vaccination did not implicate a *fundamental* right. *See Norris v. Stanley*, \_\_\_F.3d.\_\_\_, 2021 WL 3891615 (W.D. Michigan 2021). *See also BST Holdings*, No. 21-60845 \* 18 (finding that Plaintiffs’ constitutional rights were implicated by OSHA

vaccine requirement and thereby staying it); *Louisiana v. Becerra*, No. 3:21-cv-03970 (“The Plaintiff States’ citizens will suffer irreparable injury by having a substantial burden placed on their liberty interests because they will have to choose between losing their jobs or taking the vaccine.”).

This case also raises the specific question of whether vaccinating the naturally immune constitutes a violation of those constitutional rights, since there is no compelling government interest and vaccination presents a heightened risk of harm to the COVID-19 recovered. *See supra* at 9-13. If factual inferences are made in Plaintiffs’ favor—in particular that naturally acquired immunity is on par with or superior to that induced through vaccination—then the outcome of the case may be different.

Moreover, these mandates involve new vaccines that are only EUA approved, unlike any other mandate in our nation’s history. *See infra*, Point III. Certainly, the lack of knowledge as to long-term effects the vaccines could have ought to play a role in the propriety—or legality—of mandating them.

### **C. MSU’s Policy Is Coercive Under Unconstitutional Conditions Doctrine**

Perhaps Defendants are so fortunate and well off that the threat of job loss (and commensurate income deficit) would not constitute coercion for them. But for the average American, the prospect is so grim that they will avoid it at all costs, including yielding their rights to bodily integrity and receiving a medically unnecessary and possibly harmful vaccine. The coercion here is no less than it was in *Maricopa County*, in which the loss the plaintiffs were threatened with was that to interstate travel.

Moreover, in several recent cases involving vaccine mandates, courts have found that being forced to choose between vaccination and employment constitutes irreparable harm, an implicit acknowledgment that such policies are coercive. *See BST Holdings*, No. 21-60845 \* 18 (granting preliminary injunction because the OSHA mandate “substantially burden[s] the liberty interests of reluctant individual recipients put to a choice between their job(s) and their jab(s)” which constituted a loss of constitutional freedoms and thereby irreparable injury.”); *see also Fraternal Order of Police Chicago Lodge No. 7, et al. v. City of Chicago*, Case No. 2021 CH 5276, at 3 (Circuit Court of Cook County, Ill.)(Nov. 1, 2021)(internal citations omitted), *available at* <https://news.wttw.com/sites/default/files/article/file-attachments/FOP%20v.%20City%20of%20Chicago%2011.1.21%20Order.pdf> (last visited Nov. 3, 2021) (“An award of back pay or reinstatement cannot undo a vaccine. Nothing can. ... An award in favor of the police unions would be an ‘empty victory.’ ‘Obey now, grieve later’ would be transformed into ‘obey now and forever’ without a meaningful opportunity to arbitrate.”).

Indeed, an unconstitutional conditions claim may be predicated upon denial of a benefit as opposed to the threat of a loss. *See Koontz*, 570 U.S. at 604 (“the government may not deny a benefit to a person because he exercises a constitutional right.”); *Speiser v. Randall*, 357 U.S. 513, 518 (1958) (holding that government created unconstitutional condition by denying property tax exemption for engaging in certain speech). Thus, assuming *arguendo* that employment at MSU is merely a benefit—a point that Plaintiffs

do not concede—that benefit may nonetheless serve as the basis for an unconstitutional conditions claim.

In short, dismissal of Plaintiffs’ unconstitutional conditions claim is not appropriate.

### **III. MSU’S VACCINE MANDATE IS PREEMPTED BY FEDERAL LAW**

#### **A. Plaintiffs Are Entitled to Bring Claims for Declaratory and Injunctive Relief Under 21 U.S.C. § 360bbb-3 for Violations of Their Statutory Rights to Informed Consent**

Defendants cite two cases to support the proposition that the EUA statute does not provide a private right of action, but only empowers the Secretary of the Department of Health and Human Services to enforce informed consent. Def. MTD at 18-19. Initially, Defendants’ cited cases are from the Northern District of Indiana (*Klaassen v. Board of Trustees*, 2021 WL 3073926 (July 18, 2021)) and Southern District of Texas (*Bridges v. Houston Methodist Hospital*, No. H-21-1774, 2021 WL 239994 at \*2 (S.D. Tex. June 12, 2021)), neither of which carries precedential weight in this jurisdiction. In any event, both Defendants’ arguments and *Klassen* and *Bridges* are based on a fundamental misapprehension of the legal principles at stake.

Plaintiffs acknowledge that 21 U.S.C. § 360bbb-3 does not expressly provide for a private cause of action. Nothing in the part of the statute to which Defendants point, however, suggests that Congress intended to preclude individuals from enforcing their statutory rights not to take an EUA treatment. *See* 21 U.S.C. § 360bbb-3(e)(1)(A)(ii). True, “private right of action” may not be the correct terminology for this situation.

Nevertheless, Plaintiffs may seek injunctive relief to cease the violation of their rights to informed consent under 21 U.S.C. § 360bbb-3. The right to informed consent necessarily resides with the person receiving the treatment. The EUA statute does not give that right to anyone except those who already have it, in this case, Plaintiffs.

The Supreme Court has unequivocally established that the Supremacy Clause permits individuals to seek injunctive relief in federal court against state officers in order to prevent enforcement of state laws that are preempted by federal statutes. *See Armstrong v. Exceptional Child Center*, 575 U.S. 320m 326 (2015), *citing Ex parte Young*, 209 U.S. 123, 155-56 (1908) (“if an individual claims federal law immunizes him from state regulation, the court may issue an injunction upon finding the state regulatory actions preempted.”). *See also Crosby v. National Foreign Trade Council*, 530 U.S. 363 (2000) (granting plaintiffs injunctive relief, even though federal statute that allegedly preempted state law did not create a provide right of action and so was probably not enforceable under § 1983). *Cf. Gonzaga Univ. v. Doe*, 536 U.S. 273, 282 (2002) (requiring “an unambiguously conferred right to support a cause of action brought under § 1983” *for damages*); *Board of Trustees v. Garrett*, 531 U.S. 356 (2001) (noting that Rehnquist Court limited Congress’s power to create a *damages remedy* for private plaintiffs to sue state governments for violations of federal statutes).<sup>3</sup>

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<sup>3</sup> Even the result-oriented and flawed OLC Opinion does not take the position that citizens may not contest their claims in court.

In any event, as the question has not been determined by a high court—both whether the statute allows individuals to sue for injunctive and declaratory relief under it and whether employers may mandate EUA vaccines—at the very least it is unsettled. Accordingly, dismissal of this count at this stage would be inappropriate.

Relatedly, and contrary to Defendants’ position, *see* Def. MTD at 19, *Klaassen’s* determination that “the informed consent requirement under the EUA statute only applies to medical providers,” *see* 21 U.S.C. § 360bbb-3(e)(1)(A)(ii), cannot be an accurate reading of the statute. Informed consent is an utterly hollow concept if employers can premise continued employment upon taking the product in question, and there is no evidence whatsoever that Congress intended for *any* employer—and certainly not governmental ones—to be able to circumvent the informed consent requirement. *See BST Holdings*, No. 21-60845 \* 18 (mandate “substantially burden[s] the liberty interests of reluctant individual recipients put to a choice between their job(s) and their jab(s)”).

At a minimum, and given the lack of precedent, as the question has never been addressed by courts higher than the district level, it cannot be decided at the motion to dismiss stage, at which all factual inferences are to be made in Plaintiffs’ favor.

### **B. None of the Vaccines Actually Available for Intake Has Received Full FDA Approval**

Defendants contend that MSU employees are not required to take EUA vaccines in order to maintain employment because the Pfizer Comirnaty has received full FDA

approval. They claim that Plaintiffs admit Comirnaty and BioNTech have the same formulation. *See* Def. MTD at 20.

In actuality, Plaintiffs acknowledge nothing more than that the FDA fact sheet stated that the two could be used interchangeably. Since submitting the FAC, more information (recognized by a federal court) has become available indicating that the Comirnaty and BioNTech are not, in fact, the same. To begin, Pfizer acknowledges that the two vaccines are “legally distinct,” and a federal court has concluded that the Comirnaty and BioNTech vaccines are not interchangeable “as a matter of law,” Order Denying Preliminary Injunction Motions, *John Doe v. Austin*, Case No. 3:21-cv-01211, Doc. No. 47 at 14, (N.D. Fl., Nov. 12, 2021) (concluding that BioNTech vaccines “remain ‘product[s] authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act.’”) (quoting 10 U.S.C. § 1107a(a)(1)).

The two vaccines contain a different number of ingredients: Comirnaty has eleven (11) ingredients while Pfizer-BioNTech has just ten (10) ingredients. FDA, Vaccine Information Fact Sheet for Recipients and Caregivers about COMIRNATY (COVID-19 Vaccine, mRNA) and Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) (Aug. 23, 2021), available at <https://www.fda.gov/media/151733/download> (last viewed Dec. 15, 2021).

The claim that the two vaccines are interchangeable comes from a Guidance document, which does not carry force of law. *See Christensen v. Harris County*, 529 U.S. 576, 587-88 (2000) (“Interpretations such as those in opinion letters—like

interpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law—do not warrant *Chevron*-style deference.”); *Appalachian Power v. EPA*, 208 F.3d 1015, 1028 (D.C. Cir. 2000) (guidance documents that agencies treat as de facto law are void because they did not run the notice-and-comment gauntlet) (setting aside an agency guidance document in its entirety). In any event, this “fact” must be determined at a subsequent stage, not at the motion-to-dismiss stage.

FDA cannot convert a legally distinct product that is available (the BioNTech vaccine) into a fully approved vaccine (Comirnaty) that is impossible to acquire. FDA, via a mere guidance document, is attempting to establish equivalence between what are two legally distinct vaccines. That is improper as a general matter of administrative law. It is yet more improper since it is a maneuver designed to override federal statutory rights to informed medical consent and to refuse EUA products.

It was also recognized in *Doe v. Austin*, which explained that even medical products FDA claims are interchangeable can contain different inactive ingredients, which can impact safety and effectiveness of the drug in question. *Austin*, 3:21-cv-01211 at 7 fn. 5, citing *United States v. Generix Drug Corp.*, 460 U.S. 453, 454-55 (1983).

Defendants cannot be permitted to rely on mere FDA-issued guidance documents, especially where doing so would vitiate clear statutory rights. Moreover, specifically referring to the Comirnaty Vaccine, Pfizer has admitted that there “is not



sufficient approved vaccine available for distribution to this population in its entirety at the time of the reissuance of this EUA.”

Indeed, the Task Force Guidance governing the federal mandate warns that meeting the deadlines rests exclusively on the shoulders of the employees, availability problems being no excuse at that point: “Depending on employees’ locations, they may not have all types of vaccines available to them. Agencies should encourage employees to plan ahead and allow enough time to receive all required vaccine doses before the November 8 deadline to have their second shot.” *Id.* Since the Comirnaty Vaccine, being the only fully FDA-approved vaccine, is not widely available, and certainly is not available to all members of the population including Plaintiffs, nor is the legally distinct BioNTech, the EUA statute’s sphere of operation continues to apply. Accordingly, MSU employees are effectively being coerced into taking an EUA vaccine in violation of the statute’s informed consent provision.

#### **IV. PLAINTIFFS CITED HUMAN RIGHTS LAW AS A SOURCE OF GUIDANCE, NOT AS A CAUSE OF ACTION**

Defendants argue that Plaintiffs’ alleged violations of various international treaties should be dismissed because these laws do not provide for a private right of action. *See* Def. MTD at 21. Plaintiffs did not cite to these treaties to suggest that they were bringing claims under them. Rather, the purpose was to establish that MSU’s vaccine policy, like those metastasizing throughout the nation, violate various principles of human rights law and are not in accord with constitutional or international norms.

## CONCLUSION

MSU's vaccine mandate violates Plaintiffs' constitutional and statutory rights and creates an unconstitutional condition. While Plaintiffs are confident that after fully litigating the case they will prevail, certainly making all factual inferences in their favor militates against Defendants' Motion to Dismiss. This Court should deny Defendants' Motion to Dismiss and allow Plaintiffs to prosecute their claims.

Dated: December 17, 2021

Respectfully submitted,

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### **CERTIFICATE OF COMPLIANCE**

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Dated: December 17, 2021

s/ Jenin Younes  
JENIN YOUNES  
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